Summary of the
Proficiency Testing Committee Meeting
February 4, 1997

The National Environmental Laboratory Accreditation Conference (NELAC) Proficiency Testing (PT) Committee met from 10:30 a.m. to noon Eastern Standard Time on Tuesday, February 4, 1997. The meeting was led by Ms. Andrea M. Jirka, chair, U.S. Environmental Protection Agency (USEPA). A list of action items is given in Attachment A. A list of Committee members is given in Attachment B. A copy of the session agenda is given in Attachment C.

INTRODUCTION

The purpose of the meeting was to review Appendix A, "PT Provider Acceptance Criteria," of Chapter 2. The following items were addressed:

- Introduction of Appendix A,
- Overview of Appendix A presented by Mr. Chuck Wibby, and
- Discussion of Appendix A.

INTRODUCTION TO APPENDIX A

The PT Committee chair introduced Appendix A. She stated that the purpose of the appendices is to present greater detail than is desirable in the body of the chapter. Appendices A and B are still under development by the Committee and are not considered final. The appendices should be ready for voting at the Third NELAC Annual Meeting in July.

OVERVIEW OF APPENDIX A

Mr. Wibby gave a general overview of Appendix A. His subcommittee is attempting to coordinate its efforts with the USEPA Office of Water (OW) (PE) Externalization program. Mr. Wibby indicated three goals of proficiency testing:

1. To give each laboratory comparable PT samples,
2. To establish a national database, and
3. To provide the means for making correction when a PT provider is in error.

The two parts of the PT system design include initial approval of PT providers and ongoing oversight. PT oversight is assumed to be the responsibility of one organization that is technically competent. To become eligible, a candidate PT provider must be audited for quality control (QC) systems, facilities, personnel, conflict-of-interest issues, confidentiality systems, and resources for data evaluation and report generation. Ongoing oversight will be performed through monitoring pass/fail rates of participants and reviewing sample quality.

DISCUSSION OF APPENDIX A

Section A.0

A question was raised about whether a standard has already been developed regarding the requirement for approving a PT provider. In answer, it was noted that such guidance does not exist and that the standards for PT provider performance are derived from the ISO guidelines.

A participant asked how the National Environmental Laboratory Accreditation Program (NELAP) intends to transition into current USEPA performance evaluation programs. The Committee answered that NELAP will not disrupt systems already in place but will work toward a smooth transition from one to another. NELAP also intends to support the Department of Energy (DOE) and other Federal agencies. Committee members working on Appendix A are attempting to involve others in the process, including the National Institute of Standards and Technology (NIST) and the Environmental Laboratory Advisory Board (ELAB).

A participant asked how the PT oversight board (PTOB) would be selected. Neither NELAP nor USEPA has identified who will serve on the PTOB. This is a policy decision to be made within USEPA.

Section A.1

A participant asked if there would be a PT program for the PT providers. It was noted that this would add cost and seems redundant.

It was noted that a future goal is to have traceability to samples with known concentrations. The PTOB could evaluate PT providers by their ability to determine true or expected values with reference materials. The PTOB would need to verify the analytical systems of the PT providers. In this light, an annual on-site review of the providers by the PTOB may not be sufficient. More flexibility is needed in the frequency of on-site reviews.

A question was raised about whether NIST has a role to play in the oversight process. This has not been determined, but the assumption is that the PTOB will have discretion in how to operate the program.

It was recommended that the expectations of the oversight body be defined. This could include detailed descriptions of the qualities, roles, and responsibilities of the PTOB. It was suggested that a detailed description, perhaps included as part of another appendix, is needed for the PTOB. The PTOB needs to be a respected and trusted organization.

It was suggested that portions of the ISO guidelines be included in this or another appendix to serve as reference material. Currently, these ISO criteria are referenced but not included.

Section A.2 -- Quality Systems Requirements

A participant asked if a NELAC-approved PTOB will provide the same approval process that an American National Standards Institute (ANSI)-accredited registrar does but at greater cost. What matters is that the PT provider meets ISO 9001 quality system requirements.

The Committee recommended changing the last sentence regarding the annual audit to be consistent with Section A.1

Section A.3 -- Provider Facilitators and Personnel
A participant questioned the meaning of the phrase "outside the control" in the fourth-to-the-last line. The Committee answered that it was necessary to protect and control all aspects of the process, even if some parts were performed outside the primary facilities. There was agreement that the meaning of "control" needs to be defined or described better.

It was noted that this program is breaking new ground and, therefore, stringent criteria need to be established in order to give it credibility with the States. Most States already have PT systems in place. The design of any new Federal system has to instill confidence. The criteria must be rigid and high quality and include reasonable, strong controls.

Section A4.0 -- Sample Design Review
There was concern about the time that might be required for the submission and approval of a design for new PT material. In response, it was noted that review is important to ensure that the studies meet the NELAC standards.

A participant questioned whether a design is needed for each individual PT material or for a type of PT material. Does the design deal with the physical form, formulation, and concentration? The Committee will clarify this issue.

Section A4.1
No comments were received on this section.

Section A4.2
Someone noted that a PT provider could lose approval, even if the PTOB is at fault. The Committee agreed that this section needs rewording to clarify this issue.

Section A5.0 -- Provider Conflict of Interest Requirements
It was noted that some organizations may have separate branches or units, one that is a PT provider and another that is an accredited laboratory. This situation occurs in many States. The restriction presented in Section A5.0 could present financial restraints or burdens. Chapter 6 addresses this same issue. In response, it was noted that Section A5.0 does not prohibit a company from maintaining several business components. Another reason not to be too restrictive is that the best analytical laboratories will likely be the best PT providers.

Section A.5.1
It was recommended that the last sentence be expanded for clarification. Language needs to be added to ensure that the PT provider does not defeat the system, such as "Providers will not sell, distribute, or provide samples which could compromise the integrity of the NELAC system." Language about dealing with complaints should also be added.

Section A.6.0 -- Confidentiality of PT Study Data
There is a problem with wording in the second sentence. It was suggested that this sentence be deleted and that the words "acceptable ranges" be added to the first sentence.

Section A.6.1
No comments were received on this section.

Section A.7 -- Data Review and Evaluation
A participant asked if results are pass/fail only. The Committee responded that they are. It was further noted that statistically significant test results may be valid. There are reasons why this might occur. It should be cause for review but not necessarily for exclusion.

A participant suggested discussing the national database, including its relationship to others in NELAP.

Section A.8 -- Complaints and Corrective Action
A participant commented that language is needed to explain how to handle invalid complaints. It was noted that this issue is covered in ISO 9001. This section could be reworded to: "... if complaint is deemed valid by the PTOB ... ." Complaints should be sent to the PTOB as well as to the provider.

This section raised questions about due process. Federal law indicates that you can stop a provider before due process of the law. In many States, this cannot be done.

Attachment A

ACTION ITEMS
Proficiency Testing Committee
February 4, 1997

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Item No.	Action	Date Completed
1	Language needs to be prepared that fully describes all aspects of the PTOB.	

Attachment B

LIST OF PARTICIPANTS
Proficiency Testing Committee
February 4, 1997

Name	Affiliation	Phone/Fax/E-mail
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Attachment C

AGENDA
Proficiency Testing Committee
February 4, 1997

10:30 a.m. Eastern Standard Time

1. Introduction of Committee members

2. Overview Presentation of Appendix A

3. Review of Appendix A